

**IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF TEXAS**
Sherman Division

WALMART INC.,

Plaintiff,

v.

U.S. DRUG ENFORCEMENT
ADMINISTRATION; ACTING
ADMINISTRATOR TIMOTHY J. SHEA;
U.S. DEPARTMENT OF JUSTICE;
ATTORNEY GENERAL WILLIAM P.
BARR,

Defendants.

Case No. 4:20-cv-00817-SDJ

**BRIEF OF THE NATIONAL ASSOCIATION OF CHAIN DRUG STORES
AND THE AMERICAN PHARMACISTS ASSOCIATION AS
AMICI CURIAE IN SUPPORT OF PLAINTIFF**

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TABLE OF CONTENTS

	<u>Page</u>
TABLE OF CONTENTS	i
TABLE OF AUTHORITIES	ii
INTEREST OF <i>AMICI</i>	1
INTRODUCTION	2
ARGUMENT	3
I. Pharmacists are not authorized, by training or applicable law, to supersede physicians’ medical judgment in writing prescriptions for controlled substances.	3
A. Pharmacists play a different role in patients’ care than physicians.	3
B. No law authorizes pharmacists to supersede the judgment of physicians.	4
II. The federal government’s enforcement efforts are placing pharmacists in an untenable position.	6
A. Pharmacists face professional and legal liability when they decline to fill facially valid prescriptions.	7
B. Now, because of Defendants’ enforcement approach, pharmacists also face legal liability when they fill some facially valid prescriptions.	10
III. Declaratory relief is necessary and appropriate.	13
CONCLUSION	15
CERTIFICATE OF SERVICE	17

TABLE OF AUTHORITIES

	Page(s)
Cases	
<i>Abbott Labs. v. Gardner</i> , 387 U.S. 136 (1967).....	14
<i>Gamble v. United States</i> , 139 S. Ct. 1960 (2019).....	11
<i>Lefrock v. Walgreens Co.</i> , 77 F. Supp. 3d 1199 (M.D. Fla. 2015), <i>aff'd</i> , 644 F. App'x 898 (11th Cir. 2016).....	8
<i>Linzer Prod. Corp. v. Sekar</i> , 499 F. Supp. 2d 540 (S.D.N.Y. 2007).....	14
<i>Reasor v. Walmart Stores E., L.P.</i> , No. 3:19-CV-27-CRS, 2019 WL 5597302 (W.D. Ky. Oct. 30, 2019)	8
<i>Steffel v. Thompson</i> , 415 U.S. 452 (1974).....	13
<i>Tittle v. Raines</i> , 231 F. Supp. 2d 537 (N.D. Tex. 2002), <i>aff'd</i> , 69 F. App'x 658 (5th Cir. 2003).....	13
<i>Tracbeam, LLC v. AT&T, Inc.</i> , No. 6:11-CV-96, 2013 WL 12040723 (E.D. Tex. Jan. 23, 2013).....	13
Statutes	
22 TEX. ADMIN. CODE § 295.8(a)(1).....	4
Controlled Substances Act, 21 U.S.C §§ 801–904	<i>passim</i>
Food, Drug, & Cosmetic Act of 1938, 21 U.S.C. §§ 301–399i.....	4
Patients and Communities Act of 2018, Pub. L. No. 115-271, 132 Stat. 3894	4
Texas Controlled Substances Act, TEX. HEALTH & SAFETY CODE §§ 481.001–354.....	4
Texas Dangerous Drug Act, TEX. HEALTH & SAFETY CODE §§ 483.001–.107	4
Texas Food, Drug, and Cosmetic Act, TEX. HEALTH & SAFETY CODE §§ 431.001–460	4
Texas Pharmacy Act, TEX. OCC. CODE §§ 551.001–569.006.....	4

Other Authorities

21 C.F.R. § 1306.04(a).....	3, 5, 10, 13
21 C.F.R. § 1306.05(a).....	6, 11
21 C.F.R. § 1306.06.....	5
28 C.F.R. § 50.26(a)(1).....	11
28 C.F.R. § 50.27(b)(1).....	11
Am. Med. News, <i>AMA meeting: Pharmacists warned on intruding into prescribing decisions</i> (July 1, 2013), https://tinyurl.com/y3kyaxz4	7
AMA Resolution 218: AMA Response to Pharmacy Intrusion into Medical Practice (2013), https://tinyurl.com/y6zawncj	8
Complaint, <i>Fuog v. CVS Pharmacy, Inc.</i> , No. 1:20-cv-00337-WES-LDA (D.R.I. Aug. 6, 2020)	9
Complaint, <i>Smith v. Walgreens Boots All., Inc.</i> , No. 3:20-cv-05451-JD (N.D. Cal. Aug. 6, 2020)	9, 10
Complaint, <i>United States v. Chip's Discount Drugs, Inc.</i> , No 2:20-cv-00010-LGW-BWC (S.D. Ga. Feb. 12, 2020).....	12
Complaint, <i>United States v. Rodriguez</i> , No. 19-cv-1055 (N.D. Tex. May 2, 2019)	12
Complaint, <i>United States v. Seashore Drugs, Inc.</i> , No. 7:20-cv-207 (E.D.N.C. Oct. 30, 2020).....	11
CTRS. FOR DISEASE CONTROL & PREVENTION, <i>CDC Advises Against Misapplication of the Guideline for Prescribing Opioids for Chronic Pain</i> (Apr. 24, 2019), https://tinyurl.com/yxjmsazg	12
Hannah L.F. Cooper, et al., <i>Buprenorphine dispensing in an epicenter of the U.S. opioid epidemic: A case study of the rural risk environment in Appalachian Kentucky</i> , INT'L J. OF DRUG POL'Y, https://doi.org/10.1016/j.drugpo.2020.102701	15
Letter from Richard Holt, Chair, Alaska Board of Pharmacy (Jan. 23, 2019), https://tinyurl.com/y6baplgv	9, 12
Md. Bd. of Pharmacy, <i>Board Statement Regarding Pharmacists' Refusal to Fill Prescriptions</i> , https://tinyurl.com/yxhxhadv	12
N.H. Board of Pharmacy, Board Notice (May 31, 2018), https://tinyurl.com/y5ag5dof	9

Robert J. Blendon & John M. Benson, <i>The Public and the Opioid-Abuse Epidemic</i> , 378 NEW. ENG. J. MED. 407 (2018)	6
Sherif Zaafran, MD (@szaafran), Twitter (Sept. 29, 2018, 11:29 pm), https://tinyurl.com/y5cs5rpz	8
U.S. Dep’t of Health & Human Servs., <i>Guidance for Licensed Pharmacists, COVID-19 Testing, and Immunity under the PREP Act</i> (Apr. 8, 2020), https://tinyurl.com/tg66szn	4

INTEREST OF *AMICI*

Amici are leading organizations among pharmacies and pharmacists, filling billions of prescriptions every year and helping patients use medicines correctly and safely.

The National Association of Chain Drug Stores (“NACDS”) is a non-profit, tax-exempt organization incorporated in Virginia, representing traditional drug stores, community pharmacies, supermarkets, and mass merchants with pharmacies. NACDS chain members operate over 40,000 pharmacies, and its 80 chain member companies include regional chains, with a minimum of four stores, and national companies. NACDS chain members employ nearly 3 million individuals, including 155,000 pharmacists. NACDS members also include more than 900 supplier partners and over 70 international members representing 21 countries.

The American Pharmacists Association (“APhA”), founded in 1852, is the largest association of pharmacists in the United States, and is dedicated to advancing the entire pharmacy profession. Its members include pharmacists, pharmaceutical scientists, student pharmacists, pharmacy technicians, and others interested in improving medication use and advancing patient care. APhA members provide care in all practice settings, including community pharmacies, physicians’ offices, hospitals, long-term care facilities, community health centers, managed care organizations, hospice settings, and government facilities.

Amici’s primary interest in this litigation is to maintain and enhance the safe care of patients who rely on pharmacists’ training, judgment, and professionalism. To that end, pharmacies and pharmacists need and deserve clarity regarding their obligations when filling prescriptions for controlled substances, so that they can practice their profession without the threat of liability on all sides. On behalf of their members—especially those pharmacies without in-house resources to navigate the regulatory uncertainty themselves—*Amici* respectfully ask that the Court provide that clarity.

INTRODUCTION

Pharmacists play a central and critical role in our nation’s health care system. Every day across this country, pharmacists ensure that millions of patients receive the medicines they need, along with instructions for safely using them. Whether in independent pharmacies or chain drug stores, pharmacists and their employers share the same important mission: to deliver to patients the medicines they have been prescribed by licensed practitioners.¹

Defendants’ response to the opioid crisis, however, has made it increasingly difficult for pharmacists to fulfill that mission. As described in this suit, the Drug Enforcement Administration (“DEA”), backed by the threat of enforcement by the Department of Justice (“DOJ”), has injected uncertainty about pharmacists’ obligations when filling prescriptions for controlled substances. Defendants take the position that, even when a pharmacist is presented with a facially valid prescription, written by a State-licensed, DEA-registered physician, the pharmacist may—or, in some circumstances, *must*—second-guess the prescription’s appropriateness and the physician’s medical judgment in writing it.

As *Amici* explain below, imposing such an obligation on pharmacists not only misunderstands their role; it traps them in an impossible position. On the one hand, if pharmacists countermand physicians’ orders and refuse to fill valid prescriptions, they may face disciplinary actions by licensing boards, as well as lawsuits by the prescribing physicians and patients who have been deprived of their prescribed medicines. On the other hand, if pharmacists fill a valid prescription without scrutinizing it to the DEA’s satisfaction, the DOJ has threatened them with civil and criminal liability.

¹ While healthcare professionals other than physicians have prescribing authority, for the sake of simplicity *Amici* refer herein to prescribing “physicians.”

This damned-if-you-do, damned-if-you-don't scenario exposes not just pharmacists, but the pharmacies that employ them, to uncertain liability. More troubling still, Defendants' interpretation of pharmacists' supposed duty is found nowhere in the Controlled Substances Act ("CSA"), its implementing regulations, or even the DEA's Pharmacist's Manual, published last month. The applicable regulations only impose liability on a pharmacist who "knowingly" fills a prescription outside "the usual course of professional treatment." 21 C.F.R. § 1306.04(a).

These issues are of great concern to *Amici* and their members. Defendants' overreach threatens not only the livelihoods of *Amici*'s members but, most important, the lives and health of their patients. *Amici* therefore support Walmart's request for declaratory relief.² The Court should grant summary judgment and clarify the limits of what federal law requires of pharmacists when filling prescriptions for controlled substances.

ARGUMENT

I. Pharmacists are not authorized, by training or applicable law, to supersede physicians' medical judgment in writing prescriptions for controlled substances.

A. Pharmacists play a different role in patients' care than physicians.

Pharmacists occupy a unique role in our modern health care system. As medication experts who compound and dispense prescription drugs, and educate patients and healthcare providers about them, pharmacists understand how medicines affect the human body and interact with other medicines, and whether and how medicine dosing should be altered to avoid harm or achieve a particular outcome. Pharmacists often also assist the healthcare team and patients with coordination of medications, medication management, and other patient care services. *See* TEX. OCC. CODE § 551.003(33) (defining "[p]ractice of pharmacy" to include a range of functions);

² Although *Amici* support Walmart's entire motion for partial summary judgment, this brief focuses on the first three items of requested declaratory relief.

U.S. Dep’t of Health & Human Servs., *Guidance for Licensed Pharmacists, COVID-19 Testing, and Immunity under the PREP Act* (Apr. 8, 2020) (authorizing licensed pharmacists to order and administer COVID-19 tests under federal law), <https://tinyurl.com/tg66sxn>.

With different licenses, education and training, skill sets, responsibilities, and workplaces from physicians,³ pharmacists play a vital but distinct role in a patient’s care. When a pharmacist dispenses to a patient a controlled substance that has been prescribed by a physician, the pharmacist does so based on the *physician’s* assessment of the patient’s needs. The pharmacist in that situation has not examined or diagnosed the patient, and lacks the context the physician has regarding the patient’s medical situation, records, and history.

B. No law authorizes pharmacists to supersede the judgment of physicians.

While pharmacists must comply with a myriad of State and federal statutes and regulations—and face liability if they do not—these rules do not authorize, much less require, a pharmacist to supersede the medical judgment of a physician who writes a prescription.⁴

³ Each State’s board of pharmacy licenses pharmacists, handles disciplinary matters, and adopts regulations in furtherance of their States’ pharmacy laws. *See, e.g.*, TEX. OCC. CODE §§ 552.001–.012, 554.001–.057. Pharmacists are subject to strict State-imposed educational and licensing requirements, *see, e.g., id.* § 558.051(2), including annual continuing education, *see, e.g.*, 22 TEX. ADMIN. CODE § 295.8(a)(1).

⁴ Pharmacists must comply with relevant provisions of, among other federal laws, the CSA, 21 U.S.C §§ 801–904, and the Food, Drug, & Cosmetic Act of 1938, 21 U.S.C. §§ 301–399i. The growing awareness of addiction has generated multiple new laws in the last decade, including the Secure and Responsible Drug Disposal Act of 2010, the Comprehensive Addiction and Recovery Act of 2016, and, most recently, the Substance Use–Disorder Prevention that Promotes Opioid Recovery and Treatment (SUPPORT) for Patients and Communities Act of 2018, Pub. L. No. 115-271, 132 Stat. 3894, a comprehensive law aimed at ending the opioid crisis. Pharmacists in Texas must comply with the Texas Pharmacy Act, TEX. OCC. CODE §§ 551.001–569.006; the Texas Food, Drug, and Cosmetic Act, TEX. HEALTH & SAFETY CODE §§ 431.001–.460; the Texas Controlled Substances Act, *id.* §§ 481.001–.354; the Texas Dangerous Drug Act, *id.* §§ 483.001–.107; and other Texas Health and Safety Code provisions.

The federal law most relevant to this case, the CSA, recognizes the limited role of a pharmacist in providing patients access to prescribed controlled substances. It provides that pharmacists may not dispense controlled substances “without the written prescription of a practitioner,” 21 U.S.C. § 829(a), and that they risk criminal and civil liability if they do, *see id.* §§ 841(a), (c), 842. The CSA’s implementing regulations likewise explain that a “prescription for a controlled substance to be effective must be issued for a legitimate medical purpose by an individual practitioner acting in the usual course of his professional practice.” 21 C.F.R. § 1306.04(a). They then separately provide that a “prescription for a controlled substance may only be filled by a pharmacist, acting in the usual course of his professional practice and either registered individually or employed in a registered pharmacy, a registered central fill pharmacy, or registered institutional practitioner.” 21 C.F.R. § 1306.06.

Consistent with that division of responsibility, the regulations provide pharmacists only limited authority to exercise judgment over a controlled-substance prescription, penalizing those who fill a prescription they know to be illegitimate:

The responsibility for the proper prescribing and dispensing of controlled substances is upon the prescribing practitioner, but a corresponding responsibility rests with the pharmacist who fills the prescription. An order purporting to be a prescription issued not in the usual course of professional treatment or in legitimate and authorized research is not a prescription within the meaning and intent of section 309 of the Act (21 U.S.C. 829) and the person knowingly filling such a purported prescription, as well as the person issuing it, shall be subject to the penalties provided for violations of the provisions of law relating to controlled substances.

21 C.F.R. § 1306.04(a). Thus, under a pharmacist’s “corresponding responsibility,” a pharmacist may only be held liable if she “*knowingly fill[s]*” a “purported” prescription that was not written “in the usual course of professional treatment.” *Id.* (emphasis added).

This limitation on liability reflects the steps that pharmacists take when presented with a controlled-substance prescription. A pharmacist must inspect a prescription for indicia of facial invalidity—such as tampering, missing or incorrect information, a forged signature, or a prescribing physician who is not DEA-registered—and in those situations may refuse to fill it. *See, e.g.*, 21 C.F.R. § 1306.05(a) (listing the requirements for a valid prescription). But when a pharmacist is presented with a prescription lacking such indicia, she is hardly in a position to withhold medicine from a patient to whom it has been prescribed and thereby stand in the way of the patient’s medical care. Nor, without knowing a diagnosis or other information about the patient, is she in a position to doubt that the prescription was appropriately issued in the usual course of professional treatment. As explained below, however, that is precisely what Defendants’ enforcement strategy pressures pharmacists to do.

II. The federal government’s enforcement efforts are placing pharmacists in an untenable position.

The effects of the opioid epidemic have triggered a range of efforts, by government and industry alike, to combat opioid abuse. Although it is commonly recognized that pharmacists and pharmacies were not responsible for the crisis,⁵ *Amici* and their members have done and continue to do their part in preventing the diversion of prescription medications, reducing drug abuse, and saving lives. Unfortunately, Defendants’ own response to the opioid crisis—specifically, their aggressive targeting of pharmacists and pharmacies in their enforcement efforts—is placing pharmacists in an impossible position.

⁵ Robert J. Blendon & John M. Benson, *The Public and the Opioid-Abuse Epidemic*, 378 NEW. ENG. J. MED. 407, 410 (2018) (“[T]he public placed the most blame on doctors who inappropriately prescribe painkillers (33%) and people who sell prescription painkillers illegally (28%).”); *see also id.* at 408 (identifying as “mainly responsible” pharmaceutical companies (13%), people who take prescription painkillers (10%) and the FDA (7%)).

As *Amici* and their members are keenly aware, when pharmacists refuse to fill patients' facially valid prescriptions, they open themselves up to various forms of professional liability and legal exposure. *See* Part II.A *infra*. Despite that industry reality, Defendants are now threatening civil and criminal liability against pharmacies and pharmacists that *do fill* facially valid prescriptions, when those prescriptions (in Defendants' opinion) raise one or more purported "red flags." *See* Part II.B *infra*. This enforcement approach sweeps far broader than the rare wrongdoer who knowingly fills an illegitimate prescription. It forces all pharmacists into an untenable, damned-if-you-do, damned-if-you-don't situation with respect to every controlled-substance prescription that a patient presents.

A. Pharmacists face professional and legal liability when they decline to fill facially valid prescriptions.

Defendants' enforcement strategy ignores the existing liability that pharmacists face when they refuse to fill facially legitimate prescriptions. Pharmacies and pharmacists who do so can find themselves subject to opposition from physicians (both physician groups and individual physicians), discipline by state pharmacy boards, and lawsuits by patients.

Physician organizations. Physicians have long bristled at pharmacists' efforts to verify the appropriateness of prescriptions—even when those efforts are triggered by DEA's own efforts to curb drug abuse. *See* Am. Med. News, *AMA meeting: Pharmacists warned on intruding into prescribing decisions* (July 1, 2013) ("It is not the intent of pharmacists to intrude on medical practice, said . . . [NACDS's] vice president for public policy and regulatory affairs. He said pharmacies have had to respond to new levels of scrutiny by the [DEA], which has been investigating chain pharmacies for perceived over-dispensing of controlled substances."), <https://tinyurl.com/y3kyaxz4>. Despite that explanation, in 2013 the American Medical Association adopted a resolution, which is still in place today, condemning "inappropriate

inquiries from pharmacies to verify the medical rationale behind prescriptions, diagnoses and treatment plans [as] an interference with the practice of medicine and unwarranted.”⁶

More recently, when pharmacists have followed DEA’s suggested approach and declined to fill prescriptions, state medical boards have threatened legal or disciplinary action against them for engaging in the unauthorized practice of medicine. Here in Texas, for instance, the head of the state medical board publicly stated that no pharmacy’s “[g]uideline should override a physician’s ability to prescribe meds. That would be the unlicensed practice of medicine. . . . The [Texas Medical Board] wants to know when this happens.” Sherif Zaafran, MD (@szaafran), Twitter (Sept. 29, 2018, 11:29 pm), <https://tinyurl.com/y5cs5rpz>.

Individual physicians. Physicians also have taken direct legal action against pharmacists who decline their prescriptions, arguing that the refusal to fill them amounted to defamation. For instance, one physician alleged that “the failure to fill his patient’s prescriptions necessarily imputed illegal conduct because pharmacists are required to fill prescriptions unless the [p]harmacist has reason to know of some irregularity with the prescription.” *Reasor v. Walmart Stores E., L.P.*, No. 3:19-CV-27-CRS, 2019 WL 5597302, at *3 (W.D. Ky. Oct. 30, 2019) (internal quotation omitted). Similar cases abound, often involving statements made by pharmacists in refusing prescriptions. *See* Compl. ¶¶ 53 (collecting cases), 92 (same); *Lefrock v. Walgreens Co.*, 77 F. Supp. 3d 1199 (M.D. Fla. 2015), *aff’d*, 644 F. App’x 898 (11th Cir. 2016).

State boards of pharmacy. Licensing boards also have discouraged pharmacists from refusing to fill prescriptions, citing the health demands of patients in need of medicines and

⁶ AMA Resolution 218: AMA Response to Pharmacy Intrusion into Medical Practice (2013), <https://tinyurl.com/y6zawncj>. *See also id.* (“[I]f the inappropriate pharmacist prescription verification requirements and inquiry issues are not resolved promptly, our AMA will advocate for legislative and regulatory solutions to prohibit pharmacies and pharmacists from denying medically necessary and legitimate therapeutic treatments to patients”).

urging that “[e]xtreme caution should be used when deciding not to fill a prescription.” Letter from Richard Holt, Chair, Alaska Board of Pharmacy (Jan. 23, 2019), <https://tinyurl.com/y6baplgv>. *See also, e.g.*, N.H. Board of Pharmacy, Board Notice (May 31, 2018), <https://tinyurl.com/y5ag5dof>. But the pressure from licensing boards is more than rhetorical: they have threatened pharmacists and pharmacies with serious discipline for refusing to dispense controlled substances. The Wisconsin Pharmacy Examining Board, for example, found “evidence of professional misconduct” by a pharmacy that, because of concerns of overprescribing, had decided it would no longer fill controlled substance prescriptions from a local clinic. Wis. Pharmacy Examining Bd., *Administrative Warning*, Division of Legal Services and Compliance Case No. 17 PHM 095 (Dec. 6, 2018) [Dkt. 21-3]. Because it felt the pharmacy’s decision had “deterred pharmacists at the [p]harmacy from exercising their independent clinical judgment regarding dispensing controlled substances pursuant to a prescription order,” the board issued the pharmacy an administrative warning—and emphasized that “any subsequent similar violation may result in disciplinary action.” *Id.* Licensing boards in numerous other States have fielded similar complaints against other pharmacies and pharmacists. *See* Compl. ¶ 90.

Patients. Patients themselves also have sued pharmacies for refusing to fill prescriptions. Two class action suits filed this summer against Walgreens and CVS, for instance, allege “corporate wide discriminatory practices in refusing to fill, without a legitimate basis, valid and legal prescriptions for opioid medication,” and assert violations of the Americans with Disabilities Act and the Rehabilitation Act. Compl. ¶ 2, *Smith v. Walgreens Boots All., Inc.*, No. 3:20-cv-05451-JD (N.D. Cal. Aug. 6, 2020); Compl. ¶ 2, *Fuog v. CVS Pharmacy, Inc.*, No. 1:20-cv-00337-WES-LDA (D.R.I. Aug. 6, 2020). *Smith*, for instance, asserts that while Walgreens is “purporting to comply with federal mandates and the CDC Guidelines for opioid prescriptions,”

its policy of using a “‘Good Faith Dispensing’ checklist in connection with opioid prescriptions . . . stigmatizes and discriminates against chronic pain patients . . . through no fault of legitimate pain patients themselves or of the doctors caring for them.” Compl. ¶ 55, *Smith v. Walgreens Boots All., Inc.* Individual patients also have sued pharmacies under state law for allegedly refusing to fill facially valid prescriptions. *See, e.g.*, Compl. ¶ 92 (citing cases).

B. Now, because of Defendants’ enforcement approach, pharmacists also face legal liability when they fill some facially valid prescriptions.

As Walmart has described, *see, e.g.*, Compl. ¶¶ 121–44, Defendants have begun targeting pharmacists who fill prescriptions that purportedly present “red flags”—factors that Defendants believe indicate a prescription was not issued for a legitimate medical purpose, including certain combinations and amounts of prescribed drugs, *see* Compl. ¶¶ 60–61. According to Defendants, the presence of one or more of these “red flags” means that pharmacists exercising their “corresponding responsibility” under 21 C.F.R. § 1306.04(a) must refuse to fill the prescription unless the red flags are resolved.⁷

Defendants’ enforcement strategy forces pharmacies and pharmacists into an impossible position. Their threat of liability inappropriately pressures pharmacists—already faced with opposition for refusing to fill facially legitimate prescriptions—to second-guess physicians’ medical judgments regarding what medicines are to be dispensed. Defendants’ approach is all the more objectionable because it lacks a basis in the governing law and regulations. For these reasons, *Amici* agree with Walmart that the Court should grant declaratory relief on three issues.

⁷ Compl. ¶ 129. Defendants also contend that, to fulfill their legal obligations in dispensing medicines, pharmacists must document their resolution of any red flags. Compl. ¶ 132. Moreover, Defendants appear poised to assert that businesses operating pharmacies have special dispensing obligations, beyond those imposed on their employee pharmacists by the CSA and implementing regulations. *See* Compl. ¶ 142.

First, neither the CSA nor the implementing regulations mention “red flags,” let alone provide specific examples of them, as a basis for refusing to fill a prescription. (By contrast, the regulations do provide specific standards for the elements of a valid prescription. *See, e.g.*, 21 C.F.R. § 1306.05(a) (listing requirements)). Nor do the CSA or regulations provide a basis for liability if a pharmacist fills a prescription presenting “red flags” without documenting how issues were resolved. Instead, the DEA has discussed these factors only in correspondence and PowerPoint presentations. *See* Compl. ¶ 12. At most, those materials amount to sub-regulatory guidance, 28 C.F.R. § 50.26(a)(1), and the regulations themselves provide that noncompliance with it cannot serve as a basis for an enforcement action, *id.* § 50.27(b)(1). *Cf. Gamble v. United States*, 139 S. Ct. 1960, 1984 (2019) (“We operate in a system of written law”) (Thomas, J., concurring). Nor may Defendants use adjudicative agency decisions to create legal obligations and liability based on “red flags.” *See* Compl. ¶¶ 133–34. The Court should reject those efforts, as well as other attempts by Defendants to expand pharmacists’ exposure to liability.⁸ Instead it should declare that, consistent with existing federal law, pharmacists can only be held liable for “knowingly” filling prescriptions issued outside the usual course of professional treatment—and not for filling prescriptions without resolving (or documenting the resolution of) “red flags.”

Second, Defendants’ approach of categorically labeling certain factors as “red flags” does not allow for consideration or accommodation of individual circumstances. For instance, in a criminal complaint filed last year, the DOJ treated as a “red flag” the fact that a physician had prescribed the “trinity” of an opioid, a benzodiazepine, and a muscle relaxer; it asserted “[t]here

⁸ Defendants have even attempted in enforcement proceedings to criminalize, under *federal* law, a pharmacist’s failure to comply with a *State* law or regulation. *See, e.g.*, Compl. ¶ 21, *United States v. Seashore Drugs, Inc.*, No. 7:20-cv-207 (E.D.N.C. Oct. 30, 2020) (asserting that “acting in the usual course of pharmacy practice includes compliance with all relevant state laws and regulations”).

is no medical basis for the simultaneous prescription of any version of the three ‘trinity’ drugs.” Compl. ¶ 31, *United States v. Rodriguez*, No. 19-cv-1055 (N.D. Tex. May 2, 2019); *see also id.* ¶ 1 (characterizing defendants as not only “violating the . . . CSA” but “unlawfully practicing medicine”); Compl. ¶ 75, *United States v. Chip’s Discount Drugs, Inc.*, No 2:20-cv-00010-LGW-BWC (S.D. Ga. Feb. 12, 2020) (prescriptions filled by defendants in excess of “the 90 MME/day benchmark the CDC advises clinicians to avoid” were necessarily “not . . . for a legitimate medical purpose”). Not only was the DOJ’s assertion untrue,⁹ its categorical nature is inconsistent with the individualized, case-by-case approach that pharmacists take when filling prescriptions. Further, assessing unique patient circumstances and counselling patients about the risk of drug interactions (such as between an opioid analgesic and a benzodiazepine) is exactly what the practice of pharmacy entails.¹⁰ Rather than permitting pharmacists to apply their professional judgment and skill when a patient is prescribed an opioid analgesic and a benzodiazepine, Defendants’ flawed position is that pharmacists must categorically refuse the patient access to those medications.¹¹ The Court should eliminate this uncertainty, and declare

⁹ As Walmart notes, when NACDS pressed the DEA on this assertion in *Rodriguez*, *see* Letter from Kevin N. Nicholson, NACDS to Raymond K. Brown and Loren T. Miller, DEA (July 12, 2019), the DEA appeared to disclaim the categorical approach. *See* Compl. ¶ 63 (citing Letter from Dep. Asst. Adm’r Prevoznik, DEA to Kevin N. Nicholson, NACDS (Nov. 4, 2019)).

¹⁰ *See, e.g.*, CTRS. FOR DISEASE CONTROL & PREVENTION, *CDC Advises Against Misapplication of the Guideline for Prescribing Opioids for Chronic Pain* (Apr. 24, 2019), (emphasizing “individualized assessment of the benefits and risks of opioids given the specific circumstances and unique needs of each patient”), <https://tinyurl.com/yxjmsazg>; Md. Bd. of Pharmacy, *Board Statement Regarding Pharmacists’ Refusal to Fill Prescriptions* (“Importantly, refusing to fill a prescription requires a specific, individualized assessment of the patient and/or the prescription.”), <https://tinyurl.com/yxhxxhadv>; Letter from Richard Holt, Chair, Alaska Board of Pharmacy (Jan. 23, 2019), (recognizing that “how an individual pharmacist approaches that particular situation [of refusing to fill a prescription] is unique and can be complex”), <https://tinyurl.com/y6baplgv>.

¹¹ The problem is the same with other, non-clinical “red flags” condemned by Defendants, such as payment by cash or a patient address far from the pharmacy. In such cases

that the CSA and its implementing regulations do not require pharmacists to refuse to fill entire categories of prescriptions without regard to the facts of individual cases.

Third, Defendants likewise go too far in contending that the CSA and its implementing regulations impose additional duties on businesses that operate pharmacies, beyond the duties imposed on their employee pharmacists. *See* Compl. ¶ 142. Under this theory, Defendants assert that the businesses that own pharmacies (like many of *Amici*’s members) may be exposed to liability even in situations where no individual employee pharmacist “knowingly” fills a prescription outside “the usual course of professional treatment” or without a “legitimate medical purpose.” 21 C.F.R. § 1306.04(a). This theory of liability can pressure pharmacy chains to implement global, bright-line bars on filling prescriptions in certain circumstances, which may further disable employee pharmacists from making case-by-case assessments. The Court should declare that the CSA and its implementing regulations do not impose such additional duties.

III. Declaratory relief is necessary and appropriate.

Amici agree that the declaratory relief Walmart seeks will provide pharmacists with needed clarity. As described above, Defendants’ enforcement strategy places pharmacists and the pharmacies that employ them in an untenable position—facing potential legal or professional liability whether pharmacists choose to fill a prescription or not. “This conflict puts [pharmacists] between Scylla and Charybdis” and therefore makes declaratory relief appropriate. *Tracbeam, LLC v. AT&T, Inc.*, No. 6:11-CV-96, 2013 WL 12040723, at *2 (E.D. Tex. Jan. 23, 2013).¹² Indeed, the choice that Defendants have foisted on pharmacists—abandon their

there are often legitimate explanations, making a categorical approach inappropriate and over-inclusive. *See, e.g.*, Compl. ¶ 58.

¹² *See also Steffel v. Thompson*, 415 U.S. 452, 462 (1974) (noting the predicament of the “hapless” party placed “between the Scylla of intentionally flouting state law and the Charybdis of forgoing what he believes to be constitutionally protected activity”); *Tittle v. Raines*, 231 F.

professional responsibilities or risk prosecution—is “a dilemma that it was the very purpose of the Declaratory Judgment Act to ameliorate.” *Abbott Labs. v. Gardner*, 387 U.S. 136, 152 (1967). *See also Linzer Prod. Corp. v. Sekar*, 499 F. Supp. 2d 540, 557 (S.D.N.Y. 2007) (where plaintiff was left with a “rock-and-a-hard-place choice” of engaging in conduct or “facing . . . suit,” noting that the “Declaratory Judgment Act was designed to prevent such situations”). Without clarity about their legal obligations and the role they should play, pharmacists and the pharmacies that employ them will continue to face uncertain exposure to liability.

Declaratory relief is especially appropriate given that Defendants’ legal position does not depend on any statutory or regulatory text. As discussed above, it rests instead on a “red flags” approach that is, at best, unenforceable sub-regulatory guidance. That approach (not to mention its sometimes inconsistent interpretation by government officials) has injected confusion and uncertainty into an area of law that demands clarity. Without the ability to consult and interpret the law applicable to filling prescriptions—the most essential function of their jobs—pharmacists and pharmacies are hamstrung in providing patient access to medically legitimate medication and, equally concerning, are subject to ever-changing enforcement whims. This Court’s grant of declaratory relief would provide needed clarity and certainty in this area, especially for those individual pharmacists and independent pharmacies who lack the resources themselves to navigate this regulatory uncertainty and avoid its pitfalls. Indeed, without guidance from this Court, many pharmacists may avoid asking questions or expressing doubts about Defendants’ approach, lest they make themselves targets for enforcement.

Supp. 2d 537, 554 n.12 (N.D. Tex. 2002) (explaining the allusion’s mythological origins), *aff’d*, 69 F. App’x 658 (5th Cir. 2003).

Finally—and perhaps most important from *Amici*’s perspective—declaratory relief is necessary because the consequences of the current uncertainty fall most heavily on the patients whose prescriptions go unfilled. The natural effect of Defendants’ position is to chill the conduct of pharmacists in filling prescriptions, even valid ones, thereby leaving patients in the lurch and without the medicines they need. This is no hypothetical concern, as illustrated by the patient suits described above and as confirmed by journalists and researchers.¹³ For the sake of millions of patients with a legitimate medical need for the controlled substances they are prescribed, *Amici* ask that the Court clear away the uncertainty that constrains their care.

CONCLUSION

Amici and their members have been and remain willing to comply with regulations that clearly and consistently define their legal obligations in filling prescriptions for controlled substances. Defendants’ position is not supported by existing regulations, however, and this Court’s intervention is necessary to clarify that. Pharmacists deserve to be able to practice their profession, serve their patients, and fill facially valid prescriptions without constant uncertainty about whether they will later be found to have violated federal law in doing so. Consequently, the Court should grant summary judgment and order Walmart’s requested declaratory relief.

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Respectfully submitted,

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¹³ As one recent study of Kentucky pharmacies found, Defendants’ aggressive enforcement efforts have had the perverse effect of causing pharmacies to restrict or refuse patients’ access to medicine used to treat opioid dependence, because they fear being reported to the DEA for “suspicious” orders. Hannah L.F. Cooper, et al., *Buprenorphine dispensing in an epicenter of the U.S. opioid epidemic: A case study of the rural risk environment in Appalachian Kentucky*, INT’L J. OF DRUG POL’Y, <https://doi.org/10.1016/j.drugpo.2020.102701>.

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CERTIFICATE OF SERVICE

I hereby certify that on the 30th day of November, 2020, I electronically filed the foregoing with the Clerk of the Court using the CM/ECF system, which will send a notification of such filing to all CM/ECF participants.

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